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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/594,164 | 09/26/2006 | Takashi Sugioka | 701061 | 7241 |
| 23460 | 7590 | 12/10/2009 | EXAMINER | |
| LEYDIG VOIT & MAYER, LTD TWO PRUDENTIAL PLAZA, SUITE 4900 180 NORTH STETSON AVENUE CHICAGO, IL 60601-6731 | | | | CLARK, SARA E |
| ART UNIT | | PAPER NUMBER | | |
| 1612 | | | | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 12/10/2009 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/594,164 | SUGIOKA ET AL. | |
| | Examiner | Art Unit | |
| | SARA E. CLARK | 1612 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 July 2009.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 18 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-18 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>7/15/2009</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

FINAL REJECTION

Receipt is acknowledged of Applicants' Amendments and Remarks, filed 7/15/2009.

Claims 1 and 8 have been amended.

The specification has been amended to correct a typographical error.

No new claims have been added.

Thus, claims 1-18 now represent all claims currently pending and under consideration.

INFORMATION DISCLOSURE STATEMENT

The information disclosure statement (IDS) submitted on 7/15/2009 was filed after the mailing date of the first action on the merits on 3/17/2009. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

WITHDRAWN OBJECTIONS/REJECTIONS

Objections

Applicant's arguments, see Remarks, p. 8, filed 7/15/2009, with respect to the objections to the specification and claims 1-18, have been fully considered and are persuasive. Therefore, the objections have been withdrawn.

Double Patenting Rejections

Applicant's arguments, see Remarks, p. 12, filed 7/15/2009, with respect to the obviousness-type double patenting rejection of instant claims 1-18 over claims 2, 4, 6, 8, and 10 of copending application 10/594,163 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

The terminal disclaimer filed on 7/15/2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on co-pending application 10/594,163 has been reviewed and is accepted. The terminal disclaimer has been approved and recorded.

MAINTAINED REJECTIONS

Rejections under 35 USC §103(a)

Claims 1-18 stand rejected under 35 USC §103(a) as obvious over Nakazawa et al. (US Pub. 2003/0181742) in view of Moriarty et al. (Tetrahedron Let. 35(44) 8103-6, 1994). See below.

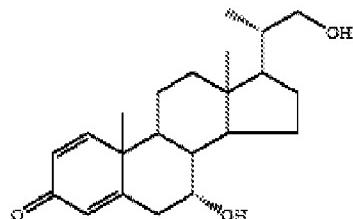
RESPONSE TO ARGUMENTS

The examiner's understanding of the inventive concept of the claimed invention is protection of the 21-hydroxyl group, the 7-hydroxyl group, or both, to suppress side reactions and decrease degradation of the catalyst, thereby decreasing the amount of catalyst required while increasing the yield. The examiner also agrees with Applicant's

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assertion that a Birch reduction (metal lithium in ammonia) does not necessarily require protection of hydroxyl groups prior to the Birch reduction step; indeed, an unprotected hydroxyl group can aid the reaction by serving as a proton donor (see Remarks, p. 10, first paragraph; and p. 11, third paragraph).

To summarize, Nakazawa et al. teach the use of lithium in a Birch reduction of the C₁-C₂ and C₄-C₅ double bonds of the unprotected compound corresponding to the claimed reactant of formula (I) (formula I-1, para. 0020),



in amounts which touch the claimed range (para. 0050, where “gram-atom” is understood as an obsolete term equivalent to “mole”):

Examples of the alkali metal usable for the above purpose are lithium, sodium, potassium and rubidium; and those of the alkali earth metals are calcium, strontium and barium. These alkali metals or alkali earth metals may be used desirably in an amount of **at least 2 gram atoms based on 1 mole of the compound (I)**, more preferably in a range of 2 to 20 gram atoms on the same basis.

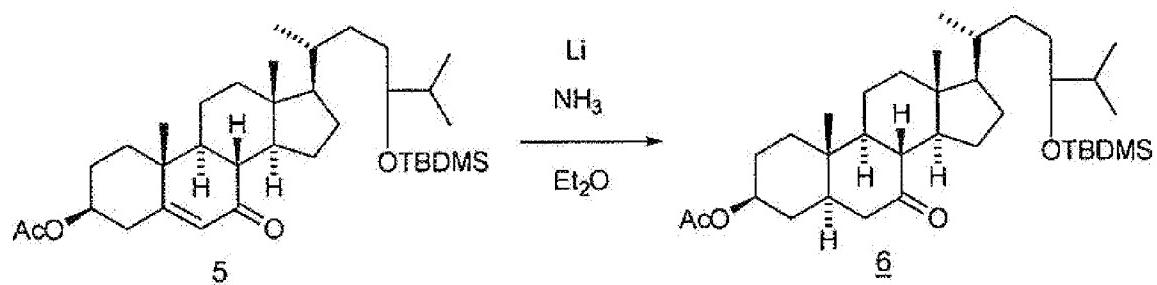
As recognized by MPEP § 2144.05,

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

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Therefore, Nakazawa et al. disclose the claimed process using the 7,21-unprotected species of the claimed compounds. Nakazawa et al. do not teach protection of the 21-hydroxyl group prior to the Birch reduction step, followed by deprotection.

However, Moriarty et al. teach protection of a 24-hydroxyl group with the claimed hydroxyl-protecting group prior to a Birch reduction, as shown in the figure provided by Applicants (Remarks, p. 10),



Applicant argues that Moriarty does not provide a credible reason for one of ordinary skill in the art to protect hydroxyl group prior to a Birch reduction (see Remarks, p. 11, third paragraph). However, Moriarty does not have to provide a reason for protecting a hydroxyl group before a Birch reduction. The issue here is whether the skilled artisan would have a reasonable expectation that the claimed reaction would run in the presence of hydroxyl protecting group. The reaction above is evidence that the skilled artisan would reasonably expect the Birch reduction to proceed in the presence of a t-butyl-dimethylsilyl hydroxyl-protecting group, regardless of the reasons contemplated by Moriarty et al. for introducing it. The reference teaches that protecting a hydroxyl group prior to a Birch reduction would not adversely affect the reaction.

Because a Birch reduction using Li/NH₃ was known to proceed successfully in either the presence or absence of hydroxyl protecting groups, one of ordinary skill in the art would have been motivated to modify the compounds of Nakazawa et al. by protecting the 21-hydroxyl group prior to the Birch reduction step with a reasonable expectation of success. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (BPAI 1985).

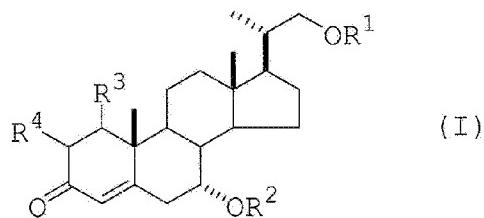
NEW REJECTIONS

Claim Rejections - 35 USC § 112, Second Paragraph

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, claims 1-18 have been amended to limit the alkali or alkaline earth metal present in the reaction to “an amount of 0.7 to 2 times the amount necessary for reducing the carbon-carbon double bond of the compound represented by formula (I),”



that is, at the 4,5-positions. However, the amount necessary to reduce the C₄-C₅ double bond is not disclosed or otherwise readily discerned. The amended specification (p. 13, lines 10-18) discloses only that:

The amount of these alkali metal or alkaline earth metal to be used is generally within the range of 0.7 to 2 times the amount necessary for reducing the carbon-carbon double bond of compound (I) to be reduced. When the amount of alkali metal or alkaline earth metal to be used is less than such range, reduction of the carbon-carbon double bond tends not to proceed sufficiently and to reduce the yield, and when it is greater than such range, side reactions (e.g., reduction of ketone and the like) tend to proceed further.

Because the amount of the alkali or alkaline earth metal to be used is defined only in relative rather than absolute terms, that is, relative to an undisclosed quantity, and not in any specific, definite way, the metes and bounds of the claims are unclear.

Claim Rejections - 35 USC § 112, First Paragraph

Written Description

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

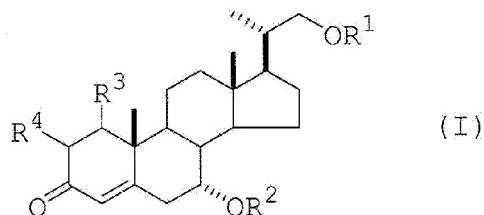
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, claims 1-18 have been amended to limit the alkali or alkaline earth metal present in the reaction to “an amount of 0.7 to 2 times the amount necessary for reducing the carbon-carbon double bond of the compound represented by formula (I),”



that is, at the 4,5-positions. However, the amount necessary to reduce the C₄-C₅ double bond is not disclosed or otherwise readily discerned. The amended specification (p. 13, lines 10-18) discloses only that:

The amount of these alkali metal or alkaline earth metal to be used is generally within the range of 0.7 to 2 times the amount necessary for reducing the carbon-carbon double bond of compound (I) to be reduced. When the amount of alkali metal or alkaline earth metal to be used is less than such range, reduction of the carbon-carbon double bond tends not to proceed sufficiently and to reduce the yield, and when it is greater than such range, side reactions (e.g., reduction of ketone and the like) tend to proceed further.

Because the amount of the alkali or alkaline earth metal to be used is defined only in relative rather than absolute terms, that is, relative to an undisclosed quantity, and not in any specific, definite way.

To illustrate, Example 1 discloses the use of 55.0 mmol lithium in the reduction of 10.9 mmol of the diene reactant, wherein R3 and R4 form a double bond (that is, to reduce the two double bonds of formula (I) to the unsaturated product of formula (II)).

Example 2 discloses the use of 24.0 mmol lithium in the reduction of 10.9 mmol the

mono-unsaturated reactant, wherein R3 and R4 are hydrogen (that is, to reduce the double bond of formula (I) to the unsaturated product of formula (II)). These amounts represent a 5.05 molar excess and a 2.20 molar excess, respectively, of lithium catalyst per mole of reactant, which may or may not fall within “an amount of 0.7 to 2 times the amount necessary for reducing the carbon-carbon double bond at the 4,5-positions” of formula (I), which simply cannot be determined on the basis of the disclosure.

The purpose of the written description requirement is to ensure that the inventor had possession of the specific subject matter claimed as of the filing date of the application. As recognized by MPEP §2163:

“To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention.” *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (“[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed”). Thus, an applicant complies with the written description requirement “by describing the invention, with all its claimed limitations, not that which makes it obvious,” and by using “such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.” *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

MPEP § 2163 identifies factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure. These include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the

claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient.

The written description requirement of 35 U.S.C. §112 requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does “little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.”) Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

CONCLUSION

Claims 1-18 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARA E. CLARK whose telephone number is (571) 270-7672. The examiner can normally be reached on Mon - Thu, 7:30 am - 5:00 pm (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SARA E. CLARK/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612